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EXAMINER	
GUGLIOTTA, NICOLE T	
ART UNIT	PAPER NUMBER
1783	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/594,918	ABE ET AL.	
	Examiner	Art Unit	
	NICOLE T. GUGLIOTTA	1783	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 August 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2, 9 - 10, 12 - 15, 28, 31 - 34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2, 9 - 10, 12 - 15, 28, 31 - 34* is/are rejected.

7)☒ Claim(s) *2* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Examiner's Note

The Examiner acknowledges the amendments to claim 2, the cancellation of claim 29 and the addition of claims 31 - 34.

Claim Objections

1. Claim 2 is objected to because of the following informalities:

Applicant's polymer chain structure 4 appears to show 2 covalent bonds branching off a central covalent bond. This is chemically incorrect. The covalent bonds should be branching off of the carbon atoms, not another covalent bond. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 2, 9 – 10, 12 - 15, 28 & 31 – 33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for "biocompatible component and the surface of the diamond-like carbon film are covalently bonded to each other", does not reasonably provide enablement for the biocompatible component and the DLC film to be bonded to each other "without a link".

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to produce the invention commensurate in scope with these claims. Applicant's specification fails to clearly define what Applicant's term "linker" of claim 2 includes. By definition, a bond is a linker. Therefore, the Examiner takes the position Applicant's claim 2 is not enabled for bonding a biocompatible component to a diamond-like carbon (DLC) film without a linker. Essentially the structure proposed would be impossible to make.

3. Claims 2, 9 - 10, 12 - 15, 28, 30 – 33 & 34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Examiner notes all the covalent bonds taught by Applicant's specification between the DLC film and the biocompatible component contain some form of functional group to allow for covalently bonding of the biocompatible component to the DLC film (specification paragraphs [0060] – [0061]). Therefore, claims 2, 9 - 10, 12 - 15, 28 & 30 – 33 are rejected.

Specifically, the Examiner points out polymer structure 4 of claim 2 (based on the compound of claim 28). Applicant's claim 28 is dependent on claim 2, which claims "the biocompatible component and the surface of the diamond-like carbon film are bonded to each other without a linker" (most recent amendment). Claim 28 specifically limits the

biocompatible component to be a polymer of hydrophilic 2-hydroxypropyl methacryl amide. However, Applicant's specific example of the polymer of hydrophilic 2-hydroxypropyl methacryl amide as the biocompatible component (specification pgs 19 – 20, paragraph [0081]) teaches an amido linkage between the polymer of hydrophilic 2-hydroxypropyl methacryl amide and the diamond-like carbon bond (DLC) film. Therefore, due to the dependence of claims 28 on claim 2, the limitation of claim 28 is considered new matter.

When considering claim 33, there is no teaching in Applicant's specification of a direct carbon-to-carbon bond between the diamond-like carbon (DLC) film and the polymer chain of the biocompatible component. Although Applicant's specification teaches graft polymerization, there is no specific teaching as to which atom of the polymer is directly grafted to the surface of the DLC film.

In regard to claim 34, Applicant's claim limitation states, "…a part of the oxygen atom is included in a hydroxyl group and another part of the oxygen atoms except the hydroxyl group are bonded to the biocompatible component."

First, the Examiner notes numerous grammatical errors in this limitation. Appropriate correction is requested.

Second, Applicant's claim limitation suggests three covalent bonds to the oxygen of the hydroxyl group: one bond from the DLC, one bond from the biocompatible component, and the third bond from the hydrogen atom of the hydroxyl group (-OH).

This is chemically incorrect because an oxygen atom comprising three covalent bonds does not have the valence electrons available to be chemically stable.

For the purpose of examination, the Examiner believes Applicant intended to claim a DLC layer surface comprising hydroxide groups (-OH), some of which have reacted with a biocompatible component to form a linker comprising oxygen (-O-) between the DLC and the biocompatible component. The Examiner has interpreted this claim limitation as such in the discussion of the prior art found below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 2, 12 – 15 & 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pacetti et al. (U.S. Patent No. 7,033,602 B1), in view of New et al. (US 2004/0127475 A1), and further in view of Dang et al. (U.S. Patent No. 6,159,531).

In regard to claims 2, 32 & 34, Pacetti et al. disclose a multilayered coating comprised of a primer, such as a diamond-like carbon (DLC) film (Col. 18, Lines 11 – 19) and a hydrogel, such as a polymer of vinyl monomers (Col. 3, Lines 32 – 35; Col. 18, Lines 20 - 21 & 28 - 32), which is applied to a medical device (base material).

Pacetti et al. are silent in regard to the specific types of vinyl monomers that may be used for the coating of their invention.

New et al. disclose biocompatible coatings for implantation devices comprised of polyvinyl esters (i.e. polyvinyl acetate), which has the chemical formula $-(CH_2\text{-}CHX)_n-$. Polyvinyl esters are biostable and minimize irritation to the vessel walls when the medical device is implanted (¶ [0061]).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use a vinyl polymer such as polyvinyl esters as the hydrogel in the invention of Pacetti et al. because New et al. teach polyvinyl esters are biostable and minimize irritation to vessel walls when the stent is implanted into the human body.

Both Pacetti et al. and New et al. are silent in regard to a covalent bond, specifically via an ester group (Applicant's "X" component of claim 2), bonding the vinyl polymers to the DLC surface.

Dang et al. teach using the oxygen of ester linkers (Col. 4, 25 – 31) for stable covalent bonds between biocompatible molecules and coatings applied to substrates (medical devices). These ester bonds enhance exposure of the biocompatible molecules to the environment. Biocompatible molecules are more likely to maintain their natural conformation and bioactivity when given the space and freedom provided by the ester bonds (Col. 4, Lines 5 – 17).

Considering the oxygen atom of the ester bonded to the DLC, the Examiner takes the position the product taught by the combination of Pacetti et al., New et al., and Dang et al. the ester is on the DLC surface and therefore a part of the DLC layer,

without a linker. New et al. also teach polyvinyl esters as part of the biocompatible component, Dang et al. teach an ester functional group attached to the DLC layer. Considering the ester groups on the surface and the biocompatible component will bond to each other, the final structural will result in a polymer chain of esters directly attached to a DLC, with no clear linker (claim 2). It would be reasonable to believe some, but not all, of the ester groups on the surface of the DLC will bond with the biocompatible component, and therefore some hydroxide groups will be free and others will react with the biocompatible component (claim 34).

Therefore, based upon the teachings of Dang et al., it would have been obvious to one of ordinary skill in the art at the time of the invention to provide an ester group (Applicant's "X" component) between the DLC film and the biocompatible material (i.e. the polyvinyl ester chains) disclosed by Pacetti et al. such that the biocompatible material has the freedom and space to maintain their natural conformation and bioactivity.

In regard to claim 12, New et al. disclose stents made of stainless steel (a metal material) (¶ [0076]).

In regard to claims 13 – 15, Pacetti et al. disclose the medical device (base material) of their invention is a stent (Col. 1, Lines 9 - 10; Col. 18, Line 4).

5. Claims 9 - 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pacetti et al. ('602), New et al. & Dang et al., as applied to claim 2 above, and further in view of Lemelson et al. (U.S. Patent No. 6,083,570).

Pacetti et al. ('602), New et al. & Dang et al. fail to disclose an intermediate layer between the medical device and the DLC layer.

Lemelson et al. disclose articles with synthetic diamond or diamond-like carbon coatings with an intermediate amorphous metal bonding layer. The residual stress in diamond and diamond-like thin film coatings applied to metal, cermet and ceramic substrates can be reduced to acceptably low levels by using an intermediate film coating of amorphous ("glassy") metal (Col. 3, Lines 54 – 65). The intermediate layer may be comprised of carbides or silicon. SiC is preferred (Col. 4, Lines 33 – 38). Such articles include dental tools and medical prostheses or implants intended for long-term use inside the human body (Col. 4, Lines 4 - 11).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention that the addition of an intermediate SiC layer between the stent and DLC thin film in the disclosure of Pacetti et al. ('602) would help to reduce the residual stress in the diamond-like carbon thin film used for medical applications. An organo-silicon intermediate layer for increased adherence between a substrate and a DLC is also disclosed by Kato et al. (U.S. Patent No. 5,763,072).

6. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pacetti et al. ('602), New et al. & Dang et al., as applied to claim 2 above, and further in view of Pacetti (US 2005/0070936 A1).

Pacetti et al. ('602), New et al. & Dang et al. fail to disclose 2-hydroxypropyl methacrylamide as a biocompatible material in the coatings of their inventions.

Pacetti ('936) discloses a medical article, such as a stent, with a coating comprising a polymer of 2-hydroxypropyl methacrylamide as a non-fouling moiety (¶ [0008] – [0009]), which is "a compound that is capable of providing the compound with the ability to prevent or at least reduce a build-up of a denatured layer of protein on the stent surface or on the stent coating" (¶ [0028]).

Therefore, based on the teachings of Pacetti ('936), it would have been obvious to one of ordinary skill in the art at the time of the invention to prevent or reduce a build-up of denatured protein by including 2-hydroxypropyl methacrylamide in the outer coating of the stent disclosed by Pacetti et al. ('602).

References of Note

7. Agrawal et al. (US 2003/0148401 A1) disclose a DLC coating on a substrate for a medical device, covalently bonded to a biomolecule, such as a small organic molecule.

8. Hossainey et al. (US 2003/0104028 A1) discloses DLC and polyvinyl acetate (chemical formula $-(CH_2\text{-}CHX)_n-$) layers on a substrate used as a medical device for implanting into a living organism.

9. Ding et al. (US 7,491,233), Fox et al. (US 2005/0069630 & Schottman et al. (US 2003/0203991) each disclose biocompatible coatings for implantation devices comprised of polyvinyl esters (i.e. polyvinyl acetate), which have the chemical formula – $(CH_2\text{-}CHX)_n$-.

10. Katoot (US 5,932,299) discloses grafting polymers by polymerization of monomers to impart characteristics of that monomer.

11. Dang et al. (US 6,159,531) teach using ester linkages for stable covalent bonds between biocompatible molecules and coatings applied to substrates, such as stents.

Response to Arguments

12. Applicants argue, "…Applicants respectfully submit that the proper perspective for this issue under 35 U.S.C. §112, first paragraph, is from one having skill in the art. In fact, an exact, verbatim description is not necessary. *See Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991). In addition, a 'patent need not teach, and preferably omits, what is well known in the art.' See, *Spectra-PHysics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1535 (Fed. Cir. 1987); *Hybritech v. Monoclonal Antibodies*, 802 F. 2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986), *cert. denied*, 107 S. Ct. 1606 (1987). In this regard, Applicants note the state of the art. Specifically, it is commonly known that a graft polymerization forms a graft polymer chain covalently bonded to a main polymer. For example, Chapter 3.2.5 'Graft Polymerization' at page 69 of the *Surface Engineering of Polymer Membranes* (Zhikang Xu, Xiaojun Huang, Lingshu Wan, ISBN 7308061698, 9787308061698, Springer (2009)[1] describes:

> Surface grafting is a chemical modification method. In surface graft polymerization, the modification is achieved by tethering suitable macromolecular chains on the membrane surface through covalent bonding.

Applicants also note FIG 3.3 on the same page 69 of *Surface Engineering of Polymer Membranes*. (Remarks, Pgs 8 – 9).

EXAMINER'S RESPONSE: Applicant's arguments with respect to the presence of forming a covalent bond during the graft polymerization process have been fully considered and are persuasive. The rejection under 35 U.S.C. § 112 of claims 2, 9 - 10, 12 - 15, 28 & 29 has been withdrawn.

13. Applicants note, "Regarding issue (2), claim 2 has been amended as shown herein. Therefore, the polymer chain of claim 28 is included into the polymer chain of claim 2. And as discussed above, grafting and covalent bonding are sufficiently described in the present specification. Applicants also note paragraph [0053] of the present specification" (Remarks, Pg 9).

14. Applicants note, "Regarding issue (3), claim 29 has been canceled, thereby rendering the rejection his claim moot" (Remarks, Pg 10).

EXAMINER'S RESPONSE: The Examiner notes Applicant's amended claim 2 and the cancellation of claim 29.

15. Applicants argue, "Dang '531 fails to teach that a bioactive/biocompatible agent is covalently linked without using multifunctional linkers. Therefore, the invention of

claims 2 and 32 are patentably distinct over the cited combination of Pacetti '602, New '475 and Dang '531" (Remarks, Pg 11).

EXAMINER'S RESPONSE: Applicant's arguments have been fully considered but they are not persuasive. As discussed above, Applicant's written description does not adequately define the term "linker". Therefore, the ester group of taught by Dang et al. can be reasonably defined as being part of the biocompatible component, which is bonded directly to the DLC film.

16. Applicants argue, "Furthermore, Dang '531 fails to show or describe a DLC film" (Remarks, Pgs 11 – 12).

EXAMINER'S RESPONSE: Applicant's arguments have been fully considered but they are not persuasive. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

17. Applicants argue, "Even if, *arguendo*, Pacetti '602, New '475, and Dang '531 were somehow combined with one another, one of ordinary skill in the art would not realize or be taught the feature that 'a biocompatible component covalently bonded to a surface of the diamond-like carbon film'" (Remarks, Pg 12).

EXAMINER'S RESPONSE: Applicant's arguments have been fully considered but they are not persuasive. As discussed above, the references above clearly teach covalent bonding of a biocompatible component to a DLC via an ester bond.

18. Applicants argue, "Regarding the second rejection, as explained on pages 6 – 7, of the Office Action, the Examiner cites Lemelson '570 to disclose the intermediate lay of pending claims 9 and 10. Applicants note that these claims depend on claim 2, wherein these dependent claims are patentable for the same reasons stated herein. The further citation of Lemelson '570 does not make the initial combination of Pacetti '602, New '475, and Dang '531 any more proper" (Remarks, Pg 12).

EXAMINER'S RESPONSE: Applicant's arguments have been fully considered but they are not persuasive. The Examiner directs Applicant to the discussion of Pacetti et al., New et al. and Dang et al. above.

19. Applicants argue, "…Pacetti '936 shows a polymer including copolymer of derivatives of EVAL (ethylene and vinyl alcohol) (see paragraph [0007] of Pacetti '936). The 2-hydroxypropyl methacryl amide is included in part of the deravatives of EVAL to improve the characteristics of EVAL, and is integrally formed with the EVAL. The EVAL is inevitable for Pacetti '936, and cannot be separated from the 2-hydroxypropyl methacryl amide. Pacetti '936 fails to teach a stent on which a polymer of 2-hydroxypropyl methacryl amide is coated. If anything, this is a teaching away" (Remarks, Pg 13).

EXAMINER'S RESPONSE: Applicant's arguments have been fully considered but they are not persuasive. The Examiner notes Applicant's claim 28 states, "…wherein the biocompatible component is a polymer of hydrophilic 2-hydroxypropyl methacryl amide". The Examiner has interpreted this limitation to mean the polymer simply comprises hydrophilic 2-hydroxypropyl methacryl amide. In addition, Pacetti '036 teach (their claim 5) that the amount of "n" (the component of the polymer comprising hydrophilic 2-hydroxypropyl methacryl amide) is as much as about 7,600. Therefore, the amount of hydrophilic 2-hydroxypropyl methacryl amide relative to the remaining parts of the polymer are relatively high. Therefore, the teachings of Pacetti '036 do not teach away from Applicant's *claimed* invention.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICOLE T. GUGLIOTTA whose telephone number is (571)270-1552. The examiner can normally be reached on M - F 8:30 a.m. - 6 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David R. Sample can be reached on 571-272-1376. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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